
OFFICE OF NEW ANIMAL DRUG EVALUATION
REVIEWERS' CHAPTER

FREEDOM OF INFORMATION (FOI) SUMMARY FOR AN ADAA FEED COMBINATION NEW ANIMAL DRUG APPLICATION (NADA)

I. PURPOSE

To describe a standardized format for the Freedom of Information Summary for an approved Animal Drug Availability Act (ADAA) Feed Combination New Animal Drug Application under 21 CFR 514.11(e)(2). [1]

II. PROCEDURE TO FOLLOW

Under 21 CFR 514.11(e), a summary of the safety and effectiveness data and information submitted or incorporated by reference must be prepared for an approved NADA. CVM may require the sponsor to prepare a summary of such data and information, which will be reviewed and revised as appropriate by CVM. Alternatively, CVM may prepare its own summary. The CVM reviewer should write the Agency Conclusions section of the FOI Summary. The reviewer should follow the procedures in the guide to ensure that the FOI summary contains necessary information in a consistent format.

The sponsor should submit the draft FOI Summary in an electronically compatible format (MSWORD preferred). If the sponsor has not done so, the primary reviewer should request it electronically (filed as an amendment). The

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[1] In 1985, CVM issued a revised FOI Summary guideline. That guideline needs to be revised, but does contain some useful information. The reviewer should follow the procedures and format outlined in this P&P guide where this guide does not match the 1985 guideline. If the reviewer has questions on any discrepancies, they should consult with their Team Leader or Division Director.

Responsible Office: ONADE Quality Assurance Team (HFV-102).
Date: 11/16/2001

electronic format allows corrections and additions to be made quickly and efficiently during the final review process, especially during processing of the approval package.

For supplemental applications, the unaffected sections of the summary should refer (by date) to the FOI summary for the original or a previous supplemental approval, as appropriate; for example, "This approval does not affect this section of the summary. Refer to FOI summary dated <*date.*>"

The following illustrates the format that should be used for an FOI summary:

III. FORMAT FOR COMBINATION NADA FOI SUMMARY

Each FOI summary should include a cover sheet that provides the following information: drug name, proprietary name, file number, sponsor name, general description of approval (species, dose), and date of approval. Reviewers, at their discretion, can include a table of contents.

This format contains the sections that should generally be addressed for ADAA feed combinations. Due to the variety of possible approvals and conditions of use for combination new animal drugs, the exact FOI format will vary. The reviewer should consult with the Team Leader or GADQC Staff for guidance on appropriate language for each section.

1. GENERAL INFORMATION:

a. File Number:	<*insert file number e.g., NADA xxx-xxx*>
b. Sponsor:	<*insert company name*> <*insert company address*> Drug Labeler Code: <*insert code number from 21 CFR 510.600*>
c. Established Name:	<*insert drug's established name*>

d.	Proprietary Name:	*<insert product's proprietary name>*
e.	Dosage Form:	*<insert dosage form>*
f.	How Supplied:	*<insert how supplied>*
g.	How Dispensed:	*<insert Rx, OTC, or VFD>*
h.	Amount of Active Ingredients:	*<insert the amount of active ingredient>*
i.	Route of Administration:	*<insert route of administration>*
j.	Species/Class:	*<insert species/class>*
k.	Recommended Dosage:	*<insert recommended dosage>*
l.	Pharmacological Category:	*<insert pharmacological category>*
m.	Indications:	*<insert indication(s) verbatim from label>*

If the summary is for a supplemental approval, include:

n.	Effect of Supplement:	*<insert effect of the action>*

2. EFFECTIVENESS:

In accordance with the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Animal Drug Availability Act of 1996, if the animal drugs/active ingredients intended for use in combination in **animal feed** have previously been separately approved for the particular uses and conditions of use for which they are intended for use in combination, FDA will not refuse to approve an NADA for the combination on effectiveness grounds unless the FDA finds that the sponsor fails to demonstrate that:

- there is substantial evidence to indicate that any active ingredient/drug intended only for the same use as another active ingredient /animal drug in combination makes a contribution to the labeled effectiveness.

- each of the active ingredients or animal drugs intended for at least one use that is different from all other active ingredients or animal drugs used in the combination provides appropriate concurrent use for the intended target population.

- where the combination contains more than one nontopical antibacterial active ingredient/animal drug, there is a substantial evidence that each of the nontopical antibacterial active ingredients/animal drugs makes a contribution to the labeled effectiveness.

You should describe each drug ingredient, the sponsor, the use and conditions of use, the CFR citation, and approved NADA identification. If the application refers to NADAs held by other sponsors, you should include the right of reference.

You should discuss how the combination approval meets the requirements set out in section 512(d)(4) of the FFDCA.

***3. TARGET ANIMAL SAFETY*:**

In accordance with the FFDCA, as amended by the Animal Drug Availability Act of 1996, if the animal drugs/active ingredients intended for use in combination in **animal feed** have previously been approved separately for the particular uses and conditions of use for which they are intended for use in combination, FDA will not refuse to approve an NADA for the combination on target animal safety grounds unless:

- there is a substantiated scientific issue specific to an active ingredient or animal drug used in the combination that cannot adequately be evaluated based on the information contained in the application for the combination, and FDA finds that the application fails to show that the combination is safe, or

- there is a scientific issue raised by target animal observations contained in the studies submitted to the NADA for the combination, and FDA finds that the application fails to show that the combination is safe.

You should describe each drug ingredient, the sponsor, the use and conditions of use, the CFR citation, and approved NADA identification. If the application refers to NADAs held by other sponsors, the FOI summary should include the right of reference. If additional information is needed to show target animal safety, describe the data provided and the basis for approval.

4. HUMAN SAFETY:

a. *If the product is to be used in a non-food-producing animal, include the following language:*

This drug is intended for use in *<insert non-food species,>* which are non-food animals. Because this new animal drug is not intended for use in food-producing animals, data on human safety, pertaining to drug residues in food, were not required for approval of this NADA.

Human Warnings are provided on the product label as follows: "Not for human use. Keep this and all drugs out of the reach of children." *<Insert any additional human warnings (including user safety concerns), as deemed appropriate.>*

b. *If the product is to be used in a food-producing animal, include the following language:*

In accordance with the FFDCA, as amended by the Animal Drug Availability Act of 1996, if the animal drugs/active ingredients intended for use in combination in animal feed have previously been approved separately for the particular uses and conditions of use for which they are intended for use in combination, FDA will not refuse to approve an NADA for the combination on human food safety grounds unless FDA finds that the application fails to establish that:

- none of the active ingredients or animal drugs used in combination at the longest withdrawal for any of the active ingredients or animal drugs in the combination exceeds the established tolerance, or

- none of the active ingredients or animal drugs in combination interferes with the method of analysis for another active ingredient or drug in the combination.

Also include the four sections listed below:

- **Toxicity:**
  <Provide a reference, by NADA number, to safety data to support the individual approvals. >

- **Tolerances for Residue:**
  <Provide a discussion on the requirement (or lack thereof) for tolerances for residue for each drug ingredient, and provide the proper CFR citation.>

- **Residue Data:**
  <Provide a complete discussion of any new tissue residue studies conducted to support the combination NADA, or citation to any pertinent studies submitted to the individual drug NADAs. Should a withdrawal period be indicated, provide a description of the needed withdrawal period.>

- **Regulatory Methods for Residues:**
  <If a withdrawal period is assigned for one or more of the drug ingredients, provide the official identification and location of the publicly available copy of the analytical method for each drug that requires a withdrawal period.>

5. AGENCY CONCLUSIONS:

The data submitted in support of this NADA satisfy the requirements of section 512(d)(4) of the FFDCA and 21 CFR Part 514 of the implementing regulations.

<Insert product name,> when administered *<insert criteria,>* is safe and effective for *<insert claim.>*

Pursuant to 21 CFR 514.106(b)(2)(vi), this combination NADA approval is regarded as a Category II supplemental change which did not require a reevaluation of safety and efficacy data in the parent NADAs.

The drugs are to be fed in Type C medicated feeds in accordance with section 2 and 3 of the FOI Summary and the Blue Bird labeling that is attached to this document.

<Provide a detailed discussion of the decision on the marketing status (Rx vs. OTC), a summary paragraph on human safety concerns, and a statement on analytical methodology (if required).>

Exclusivity is not usually applicable for ADAA combinations. In the rare case where it is needed, examples of common exclusivity situations and the paragraphs used are described in CVM Policy and Procedures Guide 1243.5780: *www.fda.gov/cvm/index/policy_proced/ppindex.html*

Ordinarily no patent information is provided for ADAA combinations; however, if Patent Information is provided, include the following:

<Drug Name> is under the following U.S. patent numbers:

U.S. Patent Number	Date of Expiration
XXXXXXXX	<insert date>

6. ATTACHMENTS:

Facsimile Labeling is attached as indicated below:
List which types of labeling are attached.

IV. DISTRIBUTION COPIES FOR FOI SUMMARY.

Copies should be distributed as follows:

cc: Courtesy copy for the sponsor (no *cc:block* listed on this copy)
HFV-199, NADA Orig. [white copy]
HFV-2, Special Mailing List
HFV-12, FOI Staff (no *cc:block* listed on this copy)
HFV-102, Reserve Copy
HFV-102, Green Book
HFV-120, Labeling Project
HFA-305, Dockets Management Branch (no *cc:block* listed on this copy)
HFR-XX999, District Office Copy

Name of Primary Reviewer

<Author's name, HFV-#, date>

NOTES:
Reviewers should send forward only one copy of the FOI Summary with the draft Approval Package.

A copy should be provided to the FDA DO for a sponsor's headquarters and for any FDA DOs identified in the HFV-140 Technical Section Complete letter or Manufacturing Chemistry Review Memoranda (as indicated in the *cc: block*). Guidance on FDA DOs is provided in CVM Policy and Procedures Guide 1243.3300, Copies of Correspondence to FDA District Offices: www.fda.gov/cvm/index/policy_proced/ppindex.html

The reviewer should provide all necessary copies in the final approval package. Copies are designate for distribution on the cover page (upper right hand corner).